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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/604,218	07/01/2003	Edwin O. Fick JR.	717119.468	1217
27128	7590	03/16/2005		EXAMINER
		BLACKWELL SANDERS PEPPER MARTIN LLP		CARRILLO, BIBI SHARIDAN
		720 OLIVE STREET		
		SUITE 2400	ART UNIT	PAPER NUMBER
		ST. LOUIS, MO 63101	1746	

DATE MAILED: 03/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/604,218	FICK ET AL.
	Examiner Sharidan Carrillo	Art Unit 1746

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 01 July 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-12 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 4-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is indefinite because it recites "inserting the needle boards", however, the claim recites a single needle board.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-2 and 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Roy (2827063).

Roy teaches a method of washing a hypodermic syringe. In reference to claim 1, Roy teaches exposing a plurality of cleaning needles mounted on a manifold 8 to a series of solutions which include a washing solution, distilled water and hot compressed air for drying. The tray 1 is transferred successively to several basins for cleaning, rinsing and drying the hypodermic syringe. In reference to claim 2, refer to col. 2, lines 50-55 and col. 3, lines 1-7. In reference to claim 4, the needle is inserted into nozzle 9

of manifold 8. The manifold is then attached to the piping means 11 for washing, rinsing, and drying the needle with a plurality of solutions. In reference to claim 5, the limitations are inherently met since the needles have to be reassembled in the syringe prior to reuse. In reference to claim 6, refer to col. 3, lines 1-7. In reference to Fig. 7, refer to element 9.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 3, and 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roy (2827063) in view of Miskin et al. (6823881).

In reference to claims 3, 8-9, and 12, Roy fails to teach the gaseous stream entering through the tip and exiting the head of the needle. Miskin et al. teach cleaning a needle 30. In col. 3, lines 30-40, Miskin teaches backflushing for further aid in the removal of contaminants from the interior surface of the needle. In col. 5, lines 5-35, Miskin teaches dislodging contaminants from the needle by flowing water in a reverse flow or back flush flow direction from the tip of the needle to the head of the needle. IN col. 5, lines 60-65, Miskin teaches using fluid and air to remove contaminants.

It would have been obvious to a person of ordinary skill in the art to have modified the method of Roy to include back flushing as taught by Miskin as a means of further enhancing the removal of contaminants from the interior surface of the needle. Additionally, it is notoriously well known in the art to use the conventional principle of backflushing for enhancing contaminant removal from surfaces (6286527, 6675664). Roy teaches flushing at the head of the needle instead of the tip. The arrangement of parts was held to have been obvious. *In re Japiske* 86 (USPQ 70, CCPA 1950). In reference to claims 10-11, refer to Fig. 10 of Roy et al.

9. Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cerra et al. (US2003/0213504A1) in view of Miskin et al. (6823881).

Cerra et al. teach a method of rinsing a plurality of needle type syringes provided in a array. In reference to claim 1, Cerra et al. teach exposing a plurality of needles 4 mounted in a manifold cavity 8 to a series of solutions (paragraphs 3, 73-74). Cerra et al. fail to teach a cleaning solution. Cerra et al. teach a rinsing solution followed by drying with a compressed gas. Miskin teaches cleaning a needle 30 with a cleaning liquid, followed by rinsing with water. It would have been within the level of the skilled artisan to have modified the method of Cerra et al., to include providing Cerra et al., with a cleaning solution, as taught by Miskin, for purposes of removing contaminants from the interior surface of the needle. In reference to claim 2, refer to paragraph 73 of Cerra et al.

In reference to claims 3, 8-9, and 12, Cerra fails to teach the gaseous stream entering through the tip and exiting the head of the needle. Miskin et al. teach cleaning a needle 30. In col. 3, lines 30-40, Miskin teaches backflushing for further aid in the removal of contaminants from the interior surface of the needle. In col. 5, lines 5-35, Miskin teaches dislodging contaminants from the needle by flowing water in a reverse flow or back flush flow direction from the tip of the needle to the head of the needle. IN col. 5, lines 60-65, Miskin teaches using fluid and air to remove contaminants.

It would have been obvious to a person of ordinary skill in the art to have modified the method of Cerra to include back flushing as taught by Miskin as a means of further enhancing the removal of contaminants from the interior surface of the needle. Additionally, it is notoriously well known in the art to use the conventional principle of backflushing for enhancing contaminant removal from surfaces (6286527, 6675664).

Cerra teaches flushing at the head of the needle instead of the tip. The arrangement of parts was held to have been obvious. *In re Japiske* 86 (USPQ 70, CCPA1950).

In reference to claim 4, Cerra teaches inserting a plurality of needles in a wash module (i.e. needle board), which is further attached to a manifold cavity 8. In reference to claim 5, Cerra teaches a manifold cavity 8 which is connected to an external source of rinsing fluid (paragraph 63). In reference to claim 6, refer to paragraph 72 of Cerra et al. In reference to claims 7 and 11, refer to paragraph 68 of Cerra. In reference to claim 10, refer to Fig. 1 of Cerra.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Howell teaches cleaning the exterior surface of a needle. Stanley teaches backflushing . Strunck et al teaches cleaning ampoules by injecting air at the tip. Casady teaches cleaning hollow tubular elements. Suechel teaches cleaning hypodermic needles. Lilienthal teaches backflushing. Cundith teaches cleaning injector needles.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharidan Carrillo whose telephone number is 571-272-1297. The examiner can normally be reached on Monday-Friday, 6:00a.m-2:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Barr can be reached on 571-272-1414. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharidan Carrillo
Primary Examiner
Art Unit 1746

bsc



SHARIDAN CARRILLO
PRIMARY EXAMINER